IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

Lisa Leavitt-Garcia, and Rolando Garcia, Wife and Husband, Plaintiffs, v. The SoyNut Butter Company, and John Does 1-3 Defendants.	))))))))))))	Case No.

COMPLAINT

COME NOW the Plaintiffs, Lisa Leavitt-Garcia and Rolando Garcia, wife and husband, by and through their attorneys of record, Newland & Newland, LLP, and Marler Clark, L.L.P., P.S., complaining of the Defendants, the SoyNut Butter Company and John Does 1-3, and allege and state as follows:

PARTIES

1. At all times relevant to this action, the Plaintiffs, Lisa Leavitt-Garcia and Rolando Garcia, a married couple, resided in Santa Clara County, California. Plaintiffs are citizens of the State of California.

2. At all times relevant to this action, Defendant The SoyNut Butter Company was an Illinois corporation with its principal place of business located at 4220 Commercial Way, Glenview, IL 60025. The SoyNut Butter Company is a citizen of the State of

Illinois. At all times relevant to this action, The SoyNut Butter Company, was a manufacturer, distributor and seller of The SoyNut Butter products to customers across the country.

3. The Defendants John Does 1-3, whose identities and citizenship are presently unknown, were involved in the manufacture, distribution, and/or sale of the product that caused Plaintiffs' associated injuries.

JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of this action pursuant to 28 USC § 1332(a) because the matter in controversy exceeds $75,000, exclusive of costs; it is between citizens of different states; and because The SoyNut Butter Company is a citizen of the State of Illinois.

5. Venue in the United States District Court for the Northern District of Illinois is proper pursuant to 28 USC § 1391(a)(1) and (2) because the SoyNut Butter Company was subject to personal jurisdiction in this judicial district at the time of the commencement of the action, and because a substantial part of the events or omissions giving rise to the Plaintiffs' claims and causes of action occurred in this judicial district.

FACTS

The Outbreak

6. The FDA and the CDC, along with state and local health officials, are investigating an outbreak of Shiga toxin-producing E. coli O157:H7 infections linked to the consumption of I.M. Healthy brand SoyNut Butter produced by The SoyNut Butter Company of Glenview, Illinois.

According to the CDC, as of March 7, 2017, a total of 16 people infected with the outbreak strain of E. coli O157:H7 were reported from nine states. The number of ill people identified in each state is as follows: Arizona, (4), California (4), Maryland (1), Missouri (1), New Jersey (1), Oregon (2), Virginia (1), Washington (1) and Wisconsin (1).

7. Eight ill people have been hospitalized, and five people developed hemolytic uremic syndrome (HUS), a potentially life-threatening type of kidney failure. Fourteen of the 16 illnesses were reported in children under the age of 18. No deaths have been reported. Known illnesses started on dates ranging from January 3, 2017 to February 22, 2017.

8. The epidemiologic evidence available to investigators indicates that I.M. Healthy SoyNut Butter is a likely source of the outbreak. In interviews conducted by state and local health department officials, ill people or their family members answered questions about the foods they ate and other exposures in the week before they became ill. All of the fifteen-people reached for interviews reported either eating I.M. Healthy brand SoyNut Butter at home (nine people) in the week before they became ill or attending a childcare center that served I.M. Healthy brand SoyNut Butter or I.M. Healthy brand granola coated with SoyNut Butter (four people). Opened and unopened containers of I.M. Healthy brand SoyNut Butter have tested positive for the outbreak strain of E. coli O157:H7.

9. The SoyNut Butter Co. has announced a voluntary recall of I.M. Healthy Original Creamy SoyNut Butter with the Best By date of 08-30-18 or 08-31-18. The recall has been expanded to include both Granola and Dixie Diner's Club Brand Carb Not Beanit Butter.

E. coli O157:H7

10. E. coli is an archetypal commensal bacterial species that lives in mammalian intestines. E. coli O157:H7 is one of thousands of serotypes Escherichia coli. The combination of letters and numbers in the name of the E. coli O157:H7 refers to the specific antigens (proteins which provoke an antibody response) found on the body and tail or flagellum respectively and

distinguish it from other types of E. coli. Most serotypes of E. coli are harmless and live as normal flora in the intestines of healthy humans and animals. The E. coli bacterium is among the most extensively studied microorganism. The testing done to distinguish E. coli O157:H7 from its other E. coli counterparts is called serotyping. Pulsed-field gel electrophoresis (PFGE), sometimes also referred to as genetic fingerprinting, is used to compare E. coli O157:H7 isolates to determine if the strains are distinguishable. A technique called multilocus variable number of tandem repeats analysis (MLVA) is used to determine precise classification when it is difficult to differentiate between isolates with indistinguishable or very similar PFGE patterns.

11. E. coli O157:H7 was first recognized as a pathogen in 1982 during an investigation into an outbreak of hemorrhagic colitis associated with consumption of hamburgers from a fast food chain restaurant. Retrospective examination of more than three thousand E. coli cultures obtained between 1973 and 1982 found only one (1) isolation with serotype O157:H7, and that was a case in 1975. In the ten (10) years that followed there were approximately thirty (30) outbreaks recorded in the United States. This number is likely misleading, however, because E. coli O157:H7 infections did not become a reportable disease in any state until 1987 when Washington became the first state to mandate its reporting to public health authorities. As a result, only the most geographically concentrated outbreak would have garnered enough notice to prompt further investigation.

12. E. coli O157:H7's ability to induce injury in humans is a result of its ability to produce numerous virulence factors, most notably Shiga-like toxins. Shiga toxin (Stx) has multiple variants (e.g. Stx1, Stx2, Stx2c), and acts like the plant toxin ricin by inhibiting protein synthesis in endothelial and other cells. Shiga toxin is one of the most potent toxins known. In addition to Shiga toxins, E. coli O157:H7 produces numerous other putative virulence factors

including proteins, which aid in the attachment and colonization of the bacteria in the intestinal wall and which can lyse red blood cells and liberate iron to help support E. coli metabolism.

13. E. coli O157:H7 evolved from enteropathogenic E. coli serotype O55:H7, a cause of non-bloody diarrhea, through the sequential acquisition of phage-encoded Stx2, a large virulence plasmid, and additional chromosomal mutations. The rate of genetic mutation of E. coli O157:H7 indicates that the common ancestor of current E. coli O157:H7 clades likely existed some 20,000 years ago. E. coli O157:H7 is a relentlessly evolving organism, constantly mutating and acquiring new characteristics, including virulence factors that make the emergence of more dangerous variants a constant threat. The CDC has emphasized the prospect of emerging pathogens as a significant public health threat for some time.

14. Although foods of a bovine origin are the most common cause of both outbreaks and sporadic cases of E. coli O157:H7 infections, outbreak of illnesses have been linked to a wide variety of food items. For example, produce has, since at least 1991, been the source of substantial numbers of outbreak-related E. coli O157:H7 infections. Other unusual vehicles for E. coli O157:H7 outbreaks have included unpasteurized juices, yogurt, dried salami, mayonnaise, raw milk, game meats, sprouts, and raw cookie dough.

15. According to a recent study, an estimated 93,094 illnesses are due to domestically acquired E. coli O157:H7 each year in the United States. Estimates of foodborne acquired O157:H7 cases result in 2,138 hospitalizations and 20 deaths annually. The colitis caused by E. coli O157:H7 is characterized by severe abdominal cramps, diarrhea that typically turns bloody within twenty-four (24) hours, and sometimes fevers. The incubation period—which is to say the time from exposure to the onset of symptoms—in outbreaks is usually reported as three (3) to

four (4) days, but may be as short as one (1) day or as long as ten (10) days. Infection can occur in people of all ages but is most common in children. The duration of an uncomplicated illness can range from one (1) to twelve (12) days. In reported outbreaks, the rate of death is 0-2%, with rates running as high as 16-35% in outbreaks involving the elderly, like those have occurred at nursing homes.

16. What makes E. coli O157:H7 remarkably dangerous is its very low infectious dose, and how relatively difficult it is to kill these bacteria. Unlike Salmonella, for example, which usually requires something approximating an "egregious food handling error, E. coli O157:H7 in ground beef that is only slightly undercooked can result in infection," as few as twenty (20) organisms may be sufficient to infect a person and, as a result, possibly kill them. And unlike generic E. coli, the O157:H7 serotype multiplies at temperatures up to 44°F, survives freezing and thawing, is heat resistant, grows at temperatures up to 111°F, resists drying, and can survive exposure to acidic environments.

17. And, finally, to make it even more of a threat, E. coli O157:H7 bacteria are easily transmitted by person-to-person contact. There is also the serious risk of cross-contamination between raw meat and other food items intended to be eaten without cooking. Indeed, a principle and consistent criticism of the USDA E. coli O157:H7 policy is the fact that it has failed to focus on the risks of cross-contamination versus that posed by so-called improper cooking. With this pathogen, there is ultimately no margin of error. It is for this precise reason that the USDA has repeatedly rejected calls from the meat industry to hold consumers primarily responsible for E. coli O157:H7 infections caused, in part, by mistakes in food handling or cooking.

Hemolytic Uremic Syndrome (HUS)

18. E. coli O157:H7 infections can lead to a severe, life-threatening complication called hemolytic uremic syndrome ("HUS"). HUS accounts for the majority of the acute and chronic illness and death caused by the bacteria. HUS occurs in 2-7% of victims, primarily children, with onset five to ten days after diarrhea begins. It is the most common cause of renal failure in children. Approximately half of the children who suffer HUS require dialysis, and at least 5% of those who survive have long-term renal impairment. The same number suffers severe brain damage. While somewhat rare, serious injury to the pancreas, resulting in death or the development of diabetes, can also occur. There is no cure or effective treatment for HUS. And, tragically, as too many parents can attest, children with HUS too often die.

19. HUS is believed to develop when the toxin from the bacteria, known as Shiga-like toxin (SLT), enters the circulation through the inflamed bowel wall. SLT, and most likely other chemical mediators, attach to receptors on the inside surface of blood vessel cells (endothelial cells) and initiate a chemical cascade that results in the formation of tiny thrombi (blood clots) within these vessels. Some organs seem more susceptible, perhaps due to the presence of increased numbers of receptors, and include the kidney, pancreas, and brain. By definition, when fully expressed, HUS presents with the triad of hemolytic anemia (destruction of red blood cells), thrombocytopenia (low platelet count), and renal failure (loss of kidney function).

20. As already noted, there is no known therapy to halt the progression of HUS. HUS is a frightening complication that even in the best American centers has a notable mortality rate. Among survivors, at least five percent will suffer end stage renal disease (ESRD) with the resultant need for dialysis or transplantation. But "[b]ecause renal failure can progress slowly over decades, the eventual incidence of ESRD cannot yet be determined." Other long-term problems include the risk for hypertension, proteinuria (abnormal amounts of protein in the urine

that can portend a decline in renal function), and reduced kidney filtration rate. Other long-term problems include the risk for hypertension, proteinuria (abnormal amounts of protein in the urine that can portend a decline in renal function), and reduced kidney filtration rate. Since the longest available follow-up studies of HUS victims are 25 years, an accurate lifetime prognosis is not really available and remains controversial. All that can be said for certain is that HUS causes permanent injury, including loss of kidney function, and it requires a lifetime of close medical monitoring.

Plaintiff Lisa Leavitt-Garcia's Consumption of I.M. Healthy SoyNut Butter and E. coli O157:H7 Infection.

21. The Plaintiffs purchased Defendant's SoyNut Butter at a Target retail store location in California. Mrs. Leavitt-Garcia consumed the product regularly in the days following purchase an before onset of her E. coli O157:H7 illness. The product, manufactured by the Defendant, was contaminated by E. coli O157:H7.

22. On or about February 21, 2017, Mrs. Leavitt-Garcia, developed painful gastrointestinal symptoms. Over the following several days, the symptoms became worse and ultimately included grossly bloody diarrhea.

23. Mrs. Leavitt-Garcia saw her primary physician on or about February 23 and 24, 2016, regarding her illness. On February 24, 2017, she was admitted to Good Samaritan Hospital in San Jose, California.

24. Mrs. Leavitt-Garcia would remain hospitalized until February 28, 2017. She was confirmed to be positive for E. coli O157:H7. She continues to recover at home and faces uncertain future medical complications.

COUNT I
(Strict Product Liability)

25. The Plaintiffs incorporate the preceding paragraphs of this Complaint, by this reference, as if each of these paragraphs were set forth here in its entirety.

26. The Defendants manufactured, distributed, and sold the adulterated SoyNut Butter that injured the Plaintiffs.

27. The Defendants manufactured a food product, including SoyNut Butter, for sale to the public.

28. Food that is contaminated by E. coli O157:H7 is unsafe when put to the use reasonably foreseeable considering the nature of the product. Namely, E. coli O157:H7 contaminated food is unfit for human consumption.

29. The I.M. Healthy brand SoyNut Butter that Plaintiffs purchased, and that Plaintiff, Lisa Leavitt-Garcia consumed, was contaminated with E. coli O157:H7 when it left the control of Defendants. Mrs. Leavitt-Garcia's consumption of the contaminated food caused her to become infected by E. coli O157:H7 and to suffer injuries as a direct and proximate result of that consumption.

30. The Defendants are strictly liable to the Plaintiffs for the harm proximately caused by the manufacture and sale of an unsafe and defective food product.

COUNT II
(Negligence)

31. The Plaintiffs incorporate the preceding paragraphs of this Complaint, by this reference, as if each of these paragraphs were set forth here in its entirety.

32. The Defendants designed, manufactured, distributed, and sold I.M. Healthy brand SoyNut Butter that was contaminated with E. coli O157:H7, a deadly pathogen.

33. The Defendants owed a duty to all persons who purchased and consumed its product, including the Plaintiffs, to manufacture and sell SoyNut Butter that was safe to eat, that was not adulterated with deadly pathogens, like E. coli O157:H7, and that was not in violation of applicable food and safety regulations. The Defendants breached this duty.

34. The Defendants owed a duty to all persons who purchased and consumed its products, including Plaintiffs, to ensure that any representations regarding the certifications its products had undergone prior to distribution and sale were made with reasonable care. Defendants breached this duty.

35. The Defendants had a duty to comply with all statutes, laws, regulations, or safety codes pertaining to the manufacture, distribution, storage, and sale of their food products, but failed to do so, and were therefore negligent. The Plaintiffs were among the class of persons designed to be protected by these statutes, laws, regulations, safety codes or provision pertaining to the manufacture, distribution, storage, and sale of similar food products.

36. The Defendants breached the duties owed to the ultimate consumers of I.M. Healthy brand SoyNut Butter by committing the following acts and omissions of negligence:

a. Failed to adequately maintain or monitor the sanitary conditions of their products, premises, equipment and employees, and the products, premises, equipment and employees of other entities in the supply chain of the subject SoyNut Butter;

b. Failed to properly operate their facilities and equipment in a safe, clean, and sanitary manner;

c. Failed to apply their food safety policies and procedures to ensure the safety and sanitary conditions of their food products, premises, and employees;

d. Failed to apply food safety policies and procedures that met industry standards for the safe and sanitary production of food products, and the safety and sanitary condition of their premises and employees;

e. Failed to prevent the transmission of E. coli O157:H7 to consumers of their SoyNut Butter;

f. Failed to properly train their employees and agents how to prevent the transmission of E. coli O157:H7 on their premises, from their facility or equipment, or in their food products;

g. Failed to properly supervise their employees and agents to prevent the transmission of E. coli O157:H7 on their premises, from their facility or equipment, or in their food products.

h. Failed to test its SoyNut Butter for microbial pathogens, like E. coli O157:H7.

37. The Defendants had a duty to comply with all statutory and regulatory provisions that pertained or applied to the manufacture, distribution, storage, labeling, and sale of their food products. The Defendants breached this duty.

38. The Defendants owed a duty to the Plaintiffs to use reasonable care in the manufacture, distribution, and sale of their food products, to prevent contamination with E. coli O157:H7. The Defendants breached this duty.

39. The Plaintiffs' injuries proximately and directly resulted from the negligence of the Defendants, and from the Defendants' violations of statutes, laws, regulations, and safety codes pertaining to the manufacture, distribution, storage, and sale of food.

COUNT III
(Breach of Warranty)

40. The Plaintiffs incorporate the preceding paragraphs of this Complaint, by this reference, as if each of these paragraphs were set forth here in its entirety.

41. By offering SoyNut Butter for sale to the public, Defendants impliedly warranted that such SoyNut Butter was safe to eat, that it was not adulterated with a deadly pathogen, and that the SoyNut Butter had been safely prepared under sanitary conditions.

42. The Defendants breached the implied warranties about the food they manufactured and sold to Plaintiffs, which was consumed by T.S., causing Plaintiffs' injuries and losses.

43. The Plaintiffs' injuries proximately and directly resulted from Defendants' breach of implied warranties, and the Plaintiffs are thus entitled to recover for all actual, consequential, and incidental damages that flow directly and in a foreseeable fashion from these breaches.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs pray as follows:

(1) That the Court award the Plaintiffs judgment against Defendants for damages.

(2) That the Court award all such other sums as shall be determined to fully and fairly compensate the Plaintiffs for all general, special, incidental and consequential damages incurred, or to be incurred, by the Plaintiffs, including loss of consortium, as the direct and proximate result of the acts and omissions of the Defendants;

(3) That the Court award the Plaintiffs their costs, disbursements and reasonable attorneys' fees incurred;

(4) That the Court award the Plaintiffs the opportunity to amend or modify the provisions of this Complaint as necessary or appropriate after additional or further discovery is completed in this matter, and after all appropriate parties have been served; and

(5) That the Court award such other and further relief as it deems necessary and proper in the circumstances.

JURY TRIAL DEMAND

Plaintiffs demand trial by jury on all issues raised herein.

Respectfully submitted,

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